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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,637

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,637	Applicant(s) GRASSET ET AL.	
	Examiner Barbara P. Badio, Ph.D.	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 34-42 is/are pending in the application.
4a) Of the above claim(s) 10,11 and 15-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9,12-14 and 34-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/7/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

First Office Action on the Merits

Election/Restrictions

1. Applicant's election with traverse of Group I, i.e., 3,5-dienes steroid derivatives in the reply filed on March 24 is acknowledged. The traversal is on the ground(s) that 4,6-dienes compounds should be examined along with the elected compounds because they are all progesterone derivatives. This is not found persuasive because they require different search strategy and, thus, a search of 3,5-dienes would not result in a reference against 4,6-dienes.

The requirement is still deemed proper and is therefore made **FINAL**.

2. Based on applicant's election of 3,5-diene compounds, claims 10, 11 and 15-21 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 1-9, 12-14 and 34-42 will be examined to the extent they read on 3,5-dienes steroids.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5, 7-9 and 34-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

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matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The court has held that an adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, “not a mere wish or plan for obtaining the claimed chemical invention.” *Eli Lilly*, 119, F.3d 1559, 1568 (Fed. Cir. 1997). The Federal Circuit has also adopted the standard set forth in the Patent and Trademark Office (“PTO”) Guidelines for Examination of Patent Applications Under the 35 USC 112, 1 “Written Description” Requirement (“Guidelines”), 66 Fed. Reg. 1099 (Jan. 5, 2001), which state that the written description requirement can be met by “showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics, “including, inter alia, “functional characteristics when coupled with a known or disclosed correlation between function and structure...”. *Enzo Biochem, Inc. v. Gen-Probe.*, 296 F.3d, 316, 1324-25 (Fed. Cir. 2002).

The instant claims encompass “compounds capable of binding to hormone receptors” comprising a nitrogen monoxide-donor nitric ester group. The present specification discloses only “steroids”, thus, indicating a distinct structural and functional property of a subset of molecules embraced by the instant claims. However, the claimed compounds are not limited to steroids. As indicated above, adequate written description requires a precise definition of the claimed invention and, thus, definition of the claimed compounds by functional language is no more than a mere wish for

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obtaining the claimed compound. The present specification does not clearly allow the skilled artisan in the art to envision the detailed chemical structure of compounds encompassed by the claimed genus of "compounds capable of binding to hormone receptors" and, thus, adequate written description is not provided for the instantly claimed invention.

5. Claims 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim contemplates the use of the claimed compounds in prevention of premature births. Claims to prevention may be unbelievable absence very strong evidence since prevention is interpreted to mean that the disease/condition will entirely cease to manifest once the claimed compound/composition is administered. However, there is no known method(s) for the determination of a person susceptible to said condition and, thus, in need of preventive treatment. Additionally, the present specification lacks guidance and/or working examples of prevention of premature birth as recited by the claimed invention. Thus, in order to practice the claimed invention commensurate in scope with the instant claims, the skilled artisan would have to search the prior art to find, if possible, a model for determining a person prone to having premature births and, thus, in need of preventive treatment. The amount of

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experimentation necessary to make said determination is undue because of the lack of guidance and/or working example in the present specification.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-9, 12-14 and 34-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite because they recite "compounds capable of binding to hormone receptors" with the only requirement that said compounds comprise a nitrogen monoxide-donor nitric ester group. However, it is unclear what is encompassed by the phrase "compounds capable of binding to hormone receptors" and, thus, the metes and bound of the claimed compounds is indefinite.

Claims 12 and 13 recites "the **hormone** capable of binding to hormone receptors". Parent claim 1 recites "a compound capable of binding to hormone receptors" and, thus, there is no antecedent basis for the above-mentioned phrase.

Claim 14 lacks a period and, thus, the metes and bound of the instant claim is indefinite.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hodosan et al. (Arzneimittel-Forschung, 1969).

Hodosan et al. teaches nitrate esters of steroid hormones including 3-ethoxyandrosta-3,5-dien-17 β -ol nitrate (see page 684, col. 2, 3rd paragraph). The compound taught by the reference is encompassed by the instant claims.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hodosan et al. (Arzneimittel-Forschung, 1969).

Hodosan et al. teaches nitrate esters of steroid hormones including 3-ethoxyandrosta-3,5-dien-17 β -ol nitrate (see page 684, col. 2, 3rd paragraph).

The instant claim differs from the reference by reciting a composition comprising a pharmaceutical carrier. However, the addition of a carrier or solvent to an unpatentable compound is prima facie obvious. See Ex parte Douros, 163 USPQ 667.

Telephone Inquiry

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio, Ph.D./
Primary Examiner, Art Unit 1612